Medtronic

PATIENT PROGRAMMER 37743

Pain therapy user manual for the Model 37701 RestorePRIME®, Model 37702 PrimeADVANCED®, Model 37711 Restore®, Model 37712 RestoreULTRA™, Model 37713 RestoreADVANCED® neurostimulation systems

! USA Rx only

CE 0123 2007

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! USA FCC Information

The following is communications regulation information on the Model 37741 Patient Programmer.

FCC ID: LF537741

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Changes or modifications to this product not authorized by Medtronic, Inc., could void the FCC Certification and negate your authority to operate this product.

Label symbols

Explanation of symbols on products and packaging. Refer to the appropriate product to see symbols that apply.

CE 0123 Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.

The use of this device might be subject to individual country licensing regimes in Europe.

System meets the applicable Canadian [C22.2-601.1-M90 (R2001)] and US (UL 60601-1:2003) electrical safety standard requirements.

Caution, consult accompanying documents

Serial number

Storage temperature

Relative humidity

Atmospheric pressure

IEC 60601-1/EN60601-1, Type BF Equipment

Non-ionizing electromagnetic radiation

Screen light

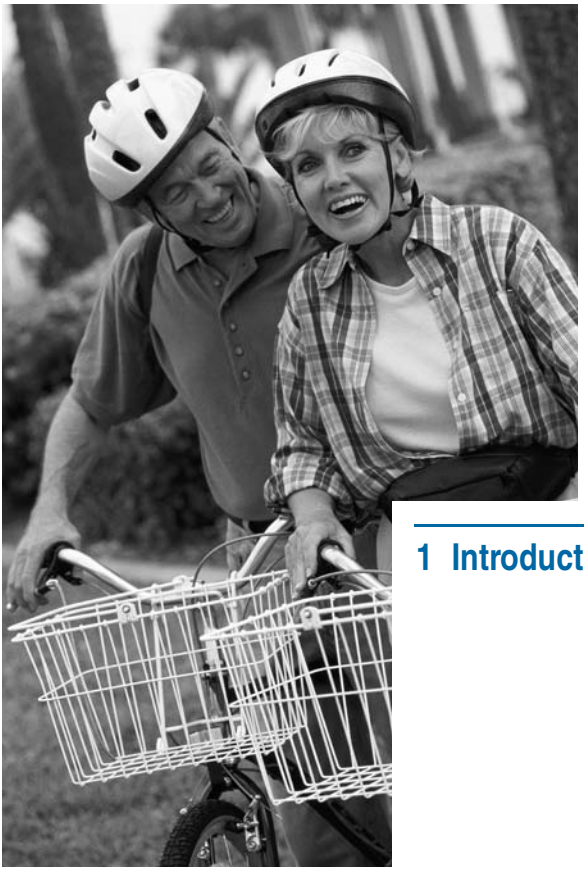
Antenna jack

For USA audiences only

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

Chinese Standard (SJ/T11364-2006) Logo: Electronic Information Products Pollution Control Symbol. (The date in this logo means the environmental protection use period of the product.)

Contents



1 Introduction

A company dedicated to patients

Medtronic was founded in 1949 by Earl Bakken, a graduate student in electrical engineering, and his brother-in-law, Palmer J. Hermundslie. Today Medtronic is the world leader in medical technology, pioneering therapies that restore health, extend life and alleviate pain.

From its modest beginnings in a 55-square meter (600-square-foot) Minneapolis garage, we have transformed Medtronic into a worldwide company that serves customers in more than 120 countries. Each year, millions of patients are treated with Medtronic products and therapies. We invest almost $500 million each year in research and development, working closely with the world's leading physicians and scientists to enhance our current products and therapies, and to

develop new ones. Although we are a large company, individual patients and their needs are still the driving force behind what we do and how we do it.

Our goal is to improve the quality of your life. This booklet, which provides information about your neurostimulation system, is one small way we try to help.

Welcome to the Medtronic family. We wish you well.

How to use this manual

Use this manual during test stimulation and after receiving an implanted neurostimulator. Ask your clinician to explain anything that is unclear.

- Chapter 1, “Introduction,” describes the patient documents your clinician should have provided to you.
- Chapter 2, “Important therapy information,” describes when you should and should not use a neurostimulation

system, and the risks, benefits, warnings, precautions, and patient activities related to your neurostimulation system.

- Chapter 3, “Introduction to stimulation,” describes the therapy, neurostimulation system components, and recovery and care information.
- Chapter 4, “Using your patient programmer,” describes the patient programmer and how to perform specific tasks.
- Chapter 5, “Troubleshooting,” describes patient programmer warning and information screens, how to solve possible problems, and who to contact if your device is lost or broken.
- Chapter 6, “Maintenance,” describes how to care for your patient programmer and system specifications.
- Appendix A provides more information about electromagnetic interference.
- A glossary is included at the end of this manual.

Patient guides

Table 1.1 on page 16 describes the documents you should receive during test stimulation and after a neurostimulator is implanted.

Note: If your implantable neurostimulator (INS) has a rechargeable battery, you should receive documents for the neurostimulator charging system.

Table 1.1 Patient guides for test stimulation and implant

Document	Test (ENS[a])	Rechargeable Implant (INS[b])	Non-rechargeable Implant (INS[b])
Medtronic Model 37022 External Neurostimulator: Test Stimulation Patient Guide. Describes the goals, activities, components and instructions for test stimulation.	✓		
Medtronic Model 37743 Patient Programmer: Pain Therapy User Manual. See page 13 for chapter details.	✓	✓	✓
Medtronic Model 37743 Patient Programmer: Quick Reference Guide. Provides instructions for common patient programmer tasks.	✓	✓	✓
Medtronic Model 37751 Recharger: Charging System User Manual. Describes the charging system and how to use it with an implanted neurostimulator.		✓	
Medtronic Model 37751 Recharger: Charging System Quick Reference Guide. Provides instructions for common charging system tasks.		✓	

Table 1.1 Patient guides for test stimulation and implant (continued)

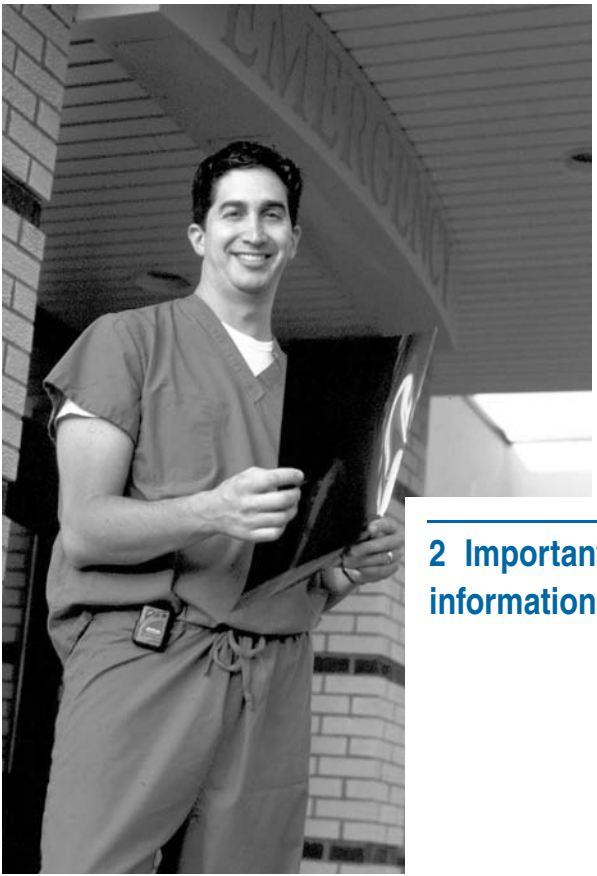
Document	Test (ENS[a])	Rechargeable Implant (INS[b])	Non-rechargeable Implant (INS[b])
Patient Identification Card. Provides information about you, your implanted neurostimulator, and your doctor.		✓	✓

[a] External neurostimulator
[b] Implantable neurostimulator

Patient identification card

When you leave the hospital, your doctor will give you a patient identification card. This card supplies information about you, your implanted device, and your doctor. Your identification card may allow you to bypass security devices. Carry this card with you at all times. If you move, change doctors, or lose your card, contact Medtronic for a replacement card. Refer to the Medtronic contacts at the end of this manual.

! USA A temporary identification card will be provided at the hospital. After Medtronic receives your implant registration from the hospital, you will receive a permanent identification card.



2 Important therapy information

Purpose of the device

The Medtronic Model 37743 Patient Programmer is designed to program the following Medtronic neurostimulators:

Rechargeable

- Model 37711 Restore
- Model 37712 RestoreULTRA
- Model 37713 RestoreADVANCED

Non-rechargeable

- Model 37701 RestorePRIME
- Model 37702 PrimeADVANCED
- Model 37022 External Neurostimulator (ENS)

Purpose of the neurostimulation system (indications)

Refer to the indications sheet that is packaged with the patient programmer for the purpose of the neurostimulation system and related information.

Therapies that may not be used with the neurostimulation system (contraindications)

Diathermy – Inform anyone treating you that you CANNOT have any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) anywhere on your body because you have an implanted neurostimulation system. Energy from diathermy can be transferred through your implanted system, and can cause tissue damage, resulting in severe injury or death. Refer to “Appendix A: Electromagnetic interference (EMI)” beginning on page 148 for more information.

Risks and benefits

Stimulation has helped thousands of patients manage their pain and improve their quality of life. Your neurostimulation system may be used with other pain treatments. Stimulation will not cure your pain. It can, however, reduce your pain to a tolerable level and allow you to resume many of your daily activities.

Risks of surgery

Implanting a neurostimulation system has risks similar to spinal procedures, including spinal fluid leak, headaches, swelling, bruising, bleeding, infection, or paralysis.

If you are on anticoagulation therapy you might be at greater risk for postoperative complications such as hematomas that could result in paralysis.

Possible adverse effects

Adverse effects of stimulation are usually mild and go away when stimulation is turned OFF. These adverse effects could include radicular chest wall stimulation, uncomfortable stimulation, a jolting or shocking sensation, or persistent pain at the neurostimulator site.

Changes in therapy

Over time there could be changes in the level of your symptom control. In most cases your doctor can correct these changes without surgery.

Possible system complications

The lead, extension, or neurostimulator could migrate within the body or erode through the skin. There could be undesirable changes in stimulation, possibly related to cellular changes around the electrode(s), changes in the position of the electrode(s), loose electrical connections, or lead or extension

fractures. It is also possible that the implanted materials could cause an allergic or immune system response.

Your neurostimulation system might unexpectedly cease to function due to battery depletion or other causes. These events, which can include electrical shorts or open circuits, conductor (wire) fractures, and insulation breaches, cannot be predicted.

Warnings

Electromagnetic interference (EMI) – Electromagnetic interference is a field of energy generated by equipment found in the home, work, medical or public environments that is strong enough to interfere with neurostimulator function. Neurostimulators include features that provide protection from EMI. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. However, strong sources of EMI can result in the following:

- Serious patient injury or death, resulting from heating of the implanted components of the neurostimulation system and damage to surrounding tissue.
- System damage, resulting in a loss of or change in symptom control and requiring additional surgery.
- Operational changes to the neurostimulator that can cause it to turn ON or OFF (particularly in a neurostimulator enabled for magnet use) or to reset to the power-on-reset (POR) values, resulting in loss of stimulation, return of underlying symptoms, and in the case of POR, requiring your health care provider to reprogram your neurostimulator.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation

could feel uncomfortable, it does not damage the device or injure a patient directly. In rare cases, as a result of the unexpected changes in stimulation, patients have fallen down and been injured.

Refer to Table 2.1, on page 27, and “Appendix A: Electromagnetic interference (EMI)” on page 147 for information on the sources of EMI, the effect of EMI on you and your neurostimulation system, and instructions on how to reduce the risk from EMI.

Table 2.1 Potential effects of EMI from devices or procedures

Device/procedure	Serious patient injury	Device damage	Momentary increase in stimulation	Device turns OFF or ON	Intermittent stimulation	See guidelines
Bone growth stimulators		✓	✓		✓	page 158
Defibrillation/ cardioversion	✓	✓	✓		✓	page 150
Dental drills and probes		✓				page 158
Diathermy, therapeutic	✓	✓			✓	page 148
Electrocautery	✓	✓				page 151
Electrolysis		✓				page 158
Electromagnetic field devices (eg, arc welding, power stations)			✓	✓	✓	page 159
High-output ultrasonics /lithotripsy		✓				page 152
Household items			✓	✓		page 162

Table 2.1 Potential effects of EMI from devices or procedures (continued)

Device/procedure	Serious patient injury	Device damage	Momentary increase in stimulation	Device turns OFF or ON	Intermittent stimulation	See guidelines
Laser procedures		✓				page 160
Magnetic resonance imaging (MRI)	✓	✓	✓	✓	✓	page 153
Psychotherapeutic procedures		✓	✓	✓	✓	page 161
Radiation therapy		✓				page 161
Radiofrequency (RF)/ microwave ablation	✓	✓			✓	page 155
Therapeutic magnets				✓		page 164
Theft detectors/security devices			✓	✓	✓	page 156

Table 2.1 Potential effects of EMI from devices or procedures (continued)

Device/procedure	Serious patient injury	Device damage	Momentary increase in stimulation	Device turns OFF or ON	Intermittent stimulation	See guidelines
Therapeutic ultrasound	✓	✓			✓	page 148
Transcutaneous electrical nerve stimulation (TENS)			✓	✓		page 161

Case damage – If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

Neurostimulator interaction with cardiac implantable devices – When a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator) are required, the doctors involved with both devices (neurologist, neurosurgeon, cardiologist, cardiac surgeon) should discuss the possible interaction between the devices before surgery. To minimize or prevent device damage or interactions, your doctors should place the devices on the opposite side of the body from one another.

- Defibrillation therapy from the implanted defibrillator can damage the neurostimulator.
- The electrical pulses from the neurostimulation system could affect the sensing operation of the cardiac device and result in inappropriate responses from the cardiac device. Your doctor

should reprogram your neurostimulator to a bipolar configuration and a minimum rate of 60 Hz. The cardiac device should be programmed to bipolar sensing.

Precautions

System and therapy

Clinician programmer interaction with a cochlear implant – If you have a cochlear implant, the external portion of the cochlear system should be kept as far away as possible from the clinician programmer or the cochlear implant should be turned OFF during programming to prevent unintended audible clicks.

Clinician programmer interaction with other active implanted devices – If you have a neurostimulator and another active implanted device, the radio-frequency signal used to program either device can reset or reprogram the other device, or the magnet in a cardiac programmer can activate magnetically controlled functions in the

neurostimulator. To verify that inadvertent programming did not occur, clinicians familiar with each device should check the programmed settings before you are sent home from the hospital and after either device is programmed (or as soon as possible after these times).

Contact your doctor immediately if you notice symptoms that could be related to either device or to the medical condition treated by that device.

Component compatibility – For proper therapy, use only Medtronic Neurological components that are prescribed by your physician.

Patient control devices – Do not place patient control devices (eg, patient programmer) over another device (eg, pacemaker, defibrillator, another neurostimulator). The patient control device could accidently change the operation of another device.

Patient device handling – To avoid damaging the device, do not immerse it in liquid; do not clean it with bleach, nail polish remover, mineral oil, or similar substances; and do not drop it or mishandle it in a way that may damage it.

Patient device use – The device is not certified for use in the presence of a flammable or anesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the device near flammable atmospheres are unknown.

Patient activities

Activities requiring excessive twisting or stretching – Avoid activities that put undue stress on the implanted components of your neurostimulation system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause parts of your neurostimulation system to fracture or migrate. This can result in a loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery. Spinal cord stimulation patients in particular should avoid excessive bending of the torso.

Component manipulation – Do not manipulate or rub your neurostimulation system through the skin; this is sometimes called “Twiddler’s Syndrome.” Manipulation can cause damage to your system, lead dislodgement, skin erosion, or stimulation at the implant site. If you have a rechargeable neurostimulator, manipulation may also flip your device so that it can’t be charged.

Scuba diving or hyperbaric chambers – Do not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water or above 2.0 ATA can damage the neurostimulation system. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor.

Skydiving, skiing, or hiking in the mountains – High altitudes should not affect the neurostimulator; however, you should consider the movements involved in any planned activity and take care to not put undue stress on your implanted neurostimulation system. During skydiving, the sudden jerking that occurs when the parachute opens can dislodge or fracture the lead, requiring additional surgery to repair or replace the lead.

Unexpected changes in stimulation – Electromagnetic interference, changes in posture, and other activities can cause a perceived increase in stimulation, which

some patients have described as uncomfortable stimulation (a jolting or shocking sensation). You should reduce your amplitude to the lowest setting and turn OFF your neurostimulator before engaging in activities that could become unsafe for you or others if you received an unexpected jolt or shock (eg, driving, operating power tools). Discuss these activities with your doctor.

Individualization of treatment

Patient management – Best results are achieved when you are fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities. Maximum benefits from the neurostimulation system require long-term postsurgical management.

Patient selection – The neurostimulation system should not be implanted if:

- your symptoms are not of physiological origin.
- you are not an appropriate candidate for surgery.
- you cannot properly operate the system.
- you do not receive satisfactory results from test stimulation.

Use in specific populations – The safety and effectiveness of this therapy has not been established for the following:

- Pregnancy, unborn fetus, or delivery
- Pediatric use (patients under the age of 18)

3 Introduction to stimulation

How stimulation works

Nerve signals from all over your body travel to your spinal cord and then to your brain. Your brain translates the signals into sensations such as pain.

Stimulation delivers electrical pulses to the area where your pain signals will be blocked as they move to the brain (Figure 3.1).

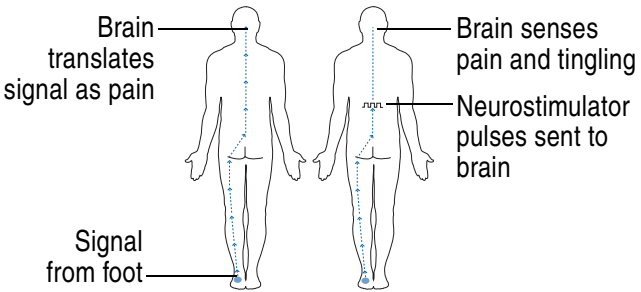


Figure 3.1 Stimulation blocks some of the pain signals as they move to the brain.

Note: Stimulation will not cure your pain, nor will it block sharp pain caused by a recent injury.

To most patients, the pulses feel like a steady, tingling sensation in the painful area (Figure 3.2).

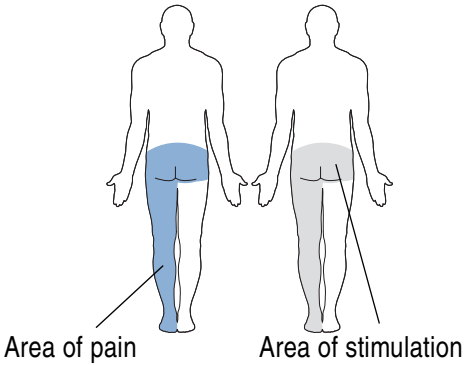


Figure 3.2 Stimulation feels like tingling in the area of pain.

Generally, people experience a fairly constant sensation of stimulation. However, you may feel changes when you suddenly move or change position.

Parts of your system

A typical neurostimulation system has implanted parts that deliver the electrical pulses to the area where your pain signals are blocked. Typically the implanted parts are: a neurostimulator, one or two leads, and one or two extensions (optional) (Figure 3.3).

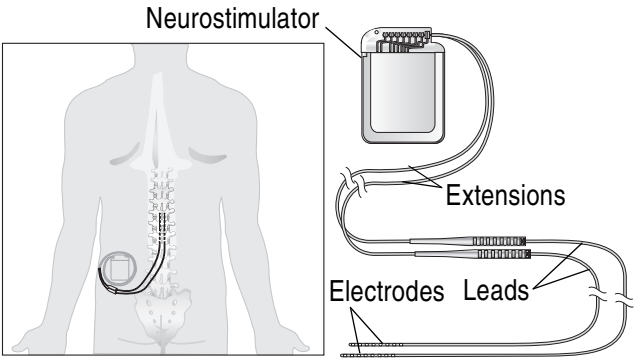


Figure 3.3 Implanted parts of a typical neurostimulation system.

A typical neurostimulation system also includes an external patient programmer for controlling your system. If you have a

rechargeable neurostimulator, your system also includes a charging system (Figure 3.4).

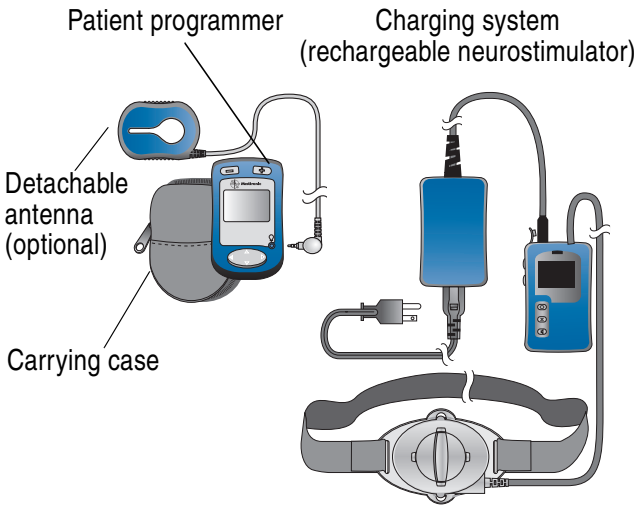


Figure 3.4 External parts of a typical neurostimulation system.

Neurostimulator – The neurostimulator is the power source (battery) for your neurostimulation system. It contains electronics that generate the electrical pulses. During test stimulation, an external neurostimulator is used to determine

whether an implanted neurostimulator is the right choice for you. The implanted neurostimulator may include a rechargeable battery:

- The implanted Model 37711 Restore, Model 37712 RestoreULTRA, and Model 37713 RestoreADVANCED neurostimulators contain rechargeable batteries.
- The implanted Model 37701 RestorePRIME and Model 37702 PrimeADVANCED neurostimulators contain non-rechargeable batteries.

Lead(s) – A lead is a set of thin wires, covered with a protective coating. A lead has small metal electrodes near the tip. The electrodes transmit electrical pulses to the area where your pain signals are blocked.

Extension(s) – An extension is a set of thin wires, covered with a protective coating, that connects the neurostimulator to a lead.

Patient programmer – A patient programmer is a hand-held device that you

use to select and adjust your stimulation. A detachable antenna is also available if you have difficulty reaching the neurostimulator implant site.

Charging system used with a rechargeable neurostimulator – The charging system is used to charge the implanted rechargeable neurostimulator battery.

Understanding your therapy

Stimulation delivers electrical pulses to the area where your pain signals will be blocked as they travel to the brain. The electrical pulses are defined by parameters called amplitude, pulse width, and rate.

- Amplitude is the strength of the pulse. It affects the stimulation strength or coverage required to manage your pain.
- Pulse width is the duration of the pulse. It affects the stimulation strength or coverage required to manage your pain.

- Rate is the number of pulses delivered per second. Rate feels like “tapping.”

A program delivers electrical pulses to a specified pain site. Programs are combined into “groups” to provide stimulation to one or more pain sites.

A menu of groups can be designed to meet a patient’s specific needs. Typically, each group is designed for particular activities, symptoms, or time of day.

For example, Alex has pain in his low back and right thigh. Typically, Alex’s pain doesn’t vary; however, sometimes Alex has additional pain in his right ankle. Alex’s clinician designed two groups for Alex to choose from. Group A is for Alex’s typical pain; group B is for the additional ankle pain (Figure 3.5). Alex chooses whichever group he requires.

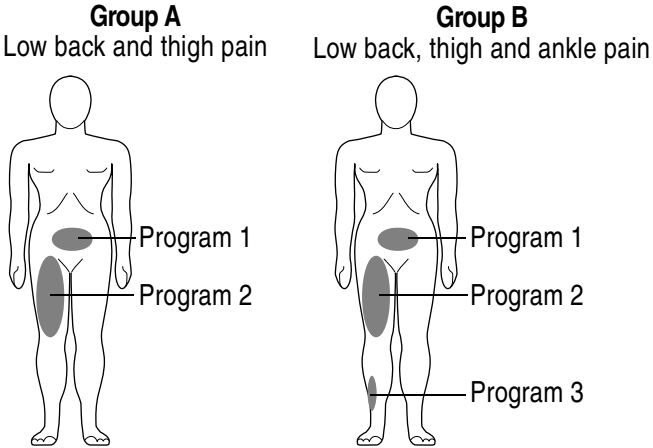


Figure 3.5 Example of programs and groups.

Controlling your stimulation

Your neurostimulator only accepts programming from the clinician programmer or patient programmer; other devices are not able to program your neurostimulator.

What your clinician controls

Your clinician uses a clinician programmer to communicate with your neurostimulator. Your clinician designs programs and groups according to your needs. Your clinician can also specify the settings that you will be able to adjust with your patient programmer. Discuss this with your clinician.

What you control

As your activities vary throughout the day, your therapy needs may change. The patient programmer allows you to turn stimulation ON and OFF, switch from one group to another, and adjust the amplitude, pulse width, or rate for each program in the active group. Talk to your clinician about the settings that apply to your therapy.

Charging a rechargeable neurostimulator

Note: This section applies only to a neurostimulator with a rechargeable battery. If your neurostimulator is non-rechargeable, continue with “Recovery and care” on page 51.

It is critical that you charge your neurostimulator battery before the battery is overdischarged. Refer to the manual packaged with the charging system for more information.

△ **Caution:** Charge the neurostimulator when you see a low battery (▭) screen on the patient programmer or recharger; this prevents the battery from overdischarging (see glossary). If the neurostimulator battery is allowed to overdischarge, charging is not possible; however, the clinician may be able to restore the battery function.

Allowing the neurostimulator battery to overdischarge will permanently affect the neurostimulator in one of the following ways:

- Battery function is restored; however, charging sessions may be more frequent because battery capacity has been reduced.
- Battery function is not restored and the neurostimulator must be surgically replaced. Battery function is not restored because:
  - The neurostimulator battery is permanently damaged.
  - The neurostimulator battery has been overdischarged and restored twice before. The third time the battery is overdischarged, the neurostimulator will reach end of service. Surgery is required to replace the neurostimulator.

Recovery and care

Recovering from surgery

It takes several weeks to heal from surgery. It is normal to feel some discomfort from the incision(s) and to have some pain at the implant site for 2 to 6 weeks.

Your doctor may also prescribe physical therapy or medication to help manage your pain. Always follow your doctor's instructions.

Activities

Some movements can cause changes in stimulation. For example, leaning back may cause the lead to move closer to your spinal cord; this can increase the sensation of stimulation. Other movements may cause the lead to move further away from your spinal cord and decrease the stimulation sensation. Sudden changes in stimulation are most common during recovery.

- Avoid activities where you must bend, stretch, or twist your body; these movements can move your leads, which affects your stimulation.
- Avoid lying on your stomach.
- Avoid reaching over your head.
- Avoid turning from side to side.
- Avoid bending forward, backward, or from side to side.
- Avoid lifting more than 2 kilograms (5 pounds).

As you begin to feel better, you should be able to perform activities such as:

- Bathing or showering
- Sexual activity
- Working at home or at your business
- Hobbies or activities, such as walking, gardening, cycling, or swimming
- Traveling

Remember, returning to your daily activities should make you feel better, not worse.

Note: As you adjust to life with better pain management, you may want to try activities that you could not perform before your surgery. Discuss your activity level with your doctor.

When to call your clinician

Contact your clinician if any of the following events occur:

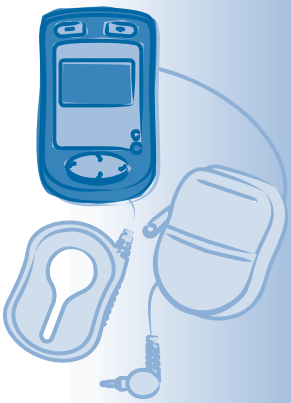
- You have pain, redness, or swelling at the incision(s) later than 6 weeks after surgery.
- You feel discomfort or pain during stimulation. Turn your neurostimulator OFF and call your doctor.
- Your system is not working properly.
- You cannot turn the neurostimulator ON or OFF.
- You cannot adjust stimulation using your patient programmer.

Care schedule

Your clinician will schedule follow-up visits to make sure you are receiving the most appropriate therapy.

4 Using your patient programmer

How the patient programmer works



The patient programmer communicates with your neurostimulator by sending signals to and receiving signals from the neurostimulator. To send and receive the signals, the internal antenna of the patient programmer must be placed over the neurostimulator (Figure 4.1).

Notes:

- The internal antenna is on the back of the patient programmer.
- The patient programmer screen must face outward.
- An optional detachable antenna is available for patients who have difficulty reaching their neurostimulator (refer to page 111).

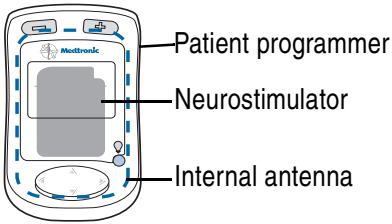


Figure 4.1 Placing the patient programmer over the neurostimulator.

The patient programmer is used to:

- turn the neurostimulator ON or OFF.
- change stimulation settings.

Note: The patient programmer can be used with all the neurostimulator models referenced in this chapter; however, the available functions will be different for each model. Be sure to note when a specific neurostimulator model is referenced to determine if the information is applicable for your neurostimulator.

Your clinician enables the available functions and specifies the settings you can adjust with

your patient programmer. Discuss this with your clinician.

Synchronizing

Synchronizing sends the settings from your neurostimulator to the patient programmer. All communication with the neurostimulator begins with synchronization.

- To synchronize your neurostimulator and the patient programmer, hold the patient programmer over your neurostimulator and press one of the three keys shown in Figure 4.2.

Note: Using the NEUROSTIMULATOR ON key to synchronize also turns ON the neurostimulator. Using the NEUROSTIMULATOR OFF key to synchronize also turns OFF the neurostimulator.

Figure 4.2 Synchronizing your neurostimulator and patient programmer.

After synchronizing, the THERAPY screen appears.

Understanding the THERAPY screen

The THERAPY screen appears on the patient programmer display after the patient programmer and neurostimulator have been synchronized (refer to “Synchronizing” on page 58). The information that appears on the THERAPY screen may be different for each patient. The information depends on which neurostimulator you have and how your clinician has programmed your neurostimulator.

Note: Figures in this chapter present information common to rechargeable and non-rechargeable neurostimulators. Some figures may display battery level icons that are unique to rechargeable neurostimulators.

Information on the THERAPY screen is arranged in three rows: the Status row, the Group row, and the Parameter row. The information on each row is represented by icons (Figure 4.3).

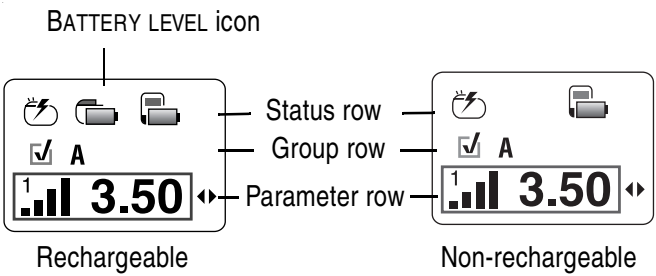


Figure 4.3 THERAPY screen.

Icons on the Status row indicate your neurostimulator status and the battery level of your patient programmer (Table 4.1 on page 62). If you have a rechargeable neurostimulator, the Status row also displays the BATTERY LEVEL icon for the rechargeable neurostimulator (Figure 4.3).

Table 4.1 Status row icons

Row	Icons	Description
Status		Neurostimulator is ON (Implanted or external neurostimulator)
		Neurostimulator is OFF (Implanted or external neurostimulator)
		Implanted rechargeable neurostimulator battery charge level
		The rechargeable implanted neurostimulator battery charge level is low
		The non-rechargeable implanted neurostimulator is near the end of service
		External neurostimulator battery level
		Patient programmer battery level

The icons on the Group row indicate the name of the group, whether or not the group is active, and whether or not your clinician

has programmed Scheduled Therapy for you (Table 4.2).

Table 4.2 Group row icons

Row	Icons	Description
Group		Active
		Not active
		Scheduled Therapy (refer to page 78)
	A, B, C, ...	Group name (icons / text)[a] (refer to page 105)
	 Walk	

[a] The icon or text on your patient programmer screen may differ. The group name will be displayed as a single letter, an icon, or text.

The icons on the Parameter row indicate the settings for your stimulation and whether or not your clinician has enabled GroupAdjust or TARGETmyStim for you (Table 4.3).

Table 4.3 Parameter row icons

Row	Icons	Description
Parameter[a]	1 (2,3,4)	Amplitude
	1 (2,3,4)	Pulse width
		Rate
		GroupAdjust (refer to page 89)
	1	TARGETmyStim (refer to page 93)

[a] If you cannot change any parameters, this row is blank.

The NAVIGATOR key on the patient programmer allows you to move between rows and display all the information for each row.

Using the NAVIGATOR key

The NAVIGATOR key (Figure 4.4) is used to navigate between and across the rows on the THERAPY screen.

Figure 4.4 NAVIGATOR key.

The selection box on the THERAPY Screen acts as a cursor to show which row is selected for programming. If there is more information on the row than can be displayed, the OPTIONS ◆▶ icon will appear next to the selection box (Figure 4.5).

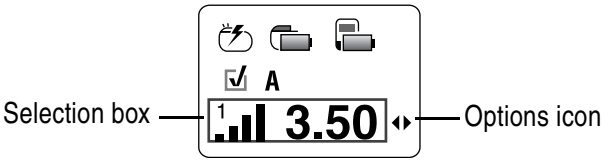


Figure 4.5 OPTIONS icon and selection box.

The NAVIGATOR key moves the selection box.The arrows on the NAVIGATOR key indicate the direction the selection box will move.

- To move the selection box between rows press the up ▲ and down ▼ arrows on the NAVIGATOR key.
- To move the selection box across a row that continues, press the left ◀ and right ▶ arrows on the NAVIGATOR key.
- When moving the selection box with the NAVIGATOR key, you do not need to hold the patient programmer over your neurostimulator. However, you must hold the patient programmer over your neurostimulator when pressing all other keys except the POWER key.

Checking batteries

Checking the external neurostimulator battery

Check the external neurostimulator battery level every day.

- To check the external neurostimulator battery level, hold the patient programmer over your neurostimulator and press the SYNC key. The THERAPY screen appears displaying the external neurostimulator battery level (Figure 4.6).

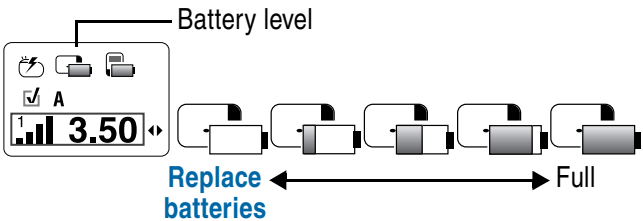
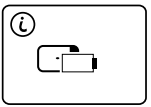
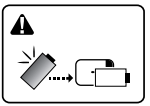


Figure 4.6 External neurostimulator battery status on the THERAPY screen.

When the batteries are low, replace the batteries as described in the external neurostimulator patient guide.

Screens indicating that the external neurostimulator batteries need immediate replacement are shown in Table 4.4

Table 4.4 External neurostimulator battery replacement screens

	The external neurostimulator batteries are low and stimulation will not be available soon. **Replace the external neurostimulator batteries. Refer to the manual packaged with the external neurostimulator.**
	The external neurostimulator batteries are depleted and stimulation is not available. **Replace the external neurostimulator batteries now. Refer to the manual packaged with the external neurostimulator.**

Checking the implanted rechargeable neurostimulator battery (Models 37711, 37712, 37713)

Check the implanted neurostimulator battery charge level every day.

- To check the implanted neurostimulator battery charge level, hold the patient programmer over your neurostimulator with the screen facing outward and press the SYNC key. The THERAPY screen appears displaying the implanted neurostimulator battery level (Figure 4.7).

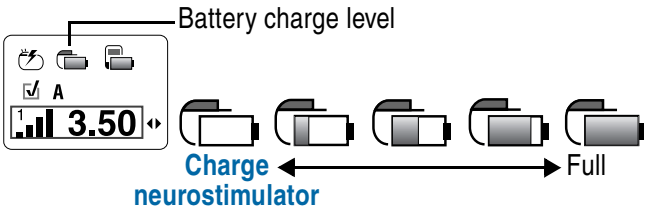


Figure 4.7 Implanted neurostimulator charge level on the THERAPY screen.

When the neurostimulator battery charge level is low, charge the battery as described in the manual packaged with the charging system. Your implanted neurostimulator battery can be charged many times; however, eventually the neurostimulator will need to be replaced.

△ **Caution:** Charge the neurostimulator when you see a low battery (▭) screen on the patient programmer or recharger; this prevents the battery from overdischarging (see glossary). If the neurostimulator battery is allowed to overdischarge, charging is not possible; however, the clinician may be able to restore the battery function.

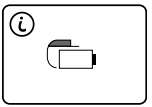
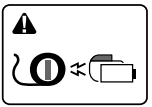
Allowing the neurostimulator battery to overdischarge will permanently affect the neurostimulator in one of the following ways:

- Battery function is restored; however, charging sessions may be more frequent because battery capacity has been reduced.

- Battery function is not restored and the neurostimulator must be surgically replaced. Battery function is not restored because:
  - The neurostimulator battery is permanently damaged.
  - The neurostimulator battery has been overdischarged and restored twice before. The third time the battery is overdischarged, the neurostimulator will reach end of service. Surgery is required to replace the neurostimulator.

If the implanted neurostimulator needs immediate charging, you will see one of the screens shown in Table 4.5.

Table 4.5 Implanted rechargeable neurostimulator battery screens

	The implanted neurostimulator battery charge level is low and stimulation will not be available soon. **Charge your implanted neurostimulator battery. Refer to the manual packaged with the charging system.** **Press any arrow on the NAVIGATOR key to clear this message from the screen.**
	The neurostimulator battery charge level is low and stimulation has stopped. **Charge the neurostimulator battery now. Refer to the manual packaged with the charging system.**

Checking the implanted non-rechargeable neurostimulator battery (Models 37701 and 37702)

- To check the implanted non-rechargeable neurostimulator battery status, hold the patient programmer over your neurostimulator with the screen facing outward and press the SYNC key. The THERAPY screen appears.

When the battery in a non-rechargeable neurostimulator is nearing depletion, the neurostimulator must be replaced to continue receiving stimulation therapy. Surgery is required to replace the non-rechargeable neurostimulator.

Screens indicating that the non-rechargeable neurostimulator battery is nearing depletion are shown in Table 4.6

Table 4.6 Implanted non-rechargeable neurostimulator battery screens

	The implanted non-rechargeable neurostimulator battery is nearing depletion and stimulation will not be available soon. **Call your clinician to schedule a visit.** **You may clear this screen and return to the THERAPY screen by pressing any arrow on the NAVIGATOR key. This screen reappears daily. After clearing this screen, a low battery level icon appears on the Status row of the THERAPY screen.**
	The implanted non-rechargeable neurostimulator battery is depleted and stimulation is not available. **Call your doctor.**

Checking the patient programmer batteries

- To check the patient programmer battery level, hold the patient programmer over your neurostimulator and press the SYNC key. The THERAPY screen appears displaying the patient programmer battery level (Figure 4.8).

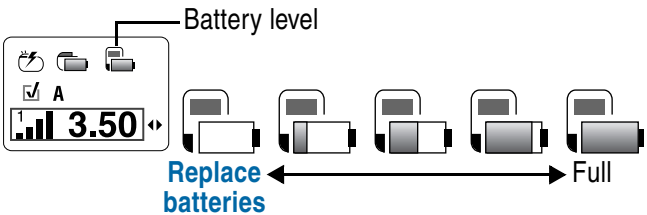
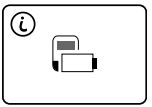
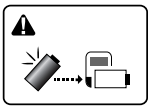


Figure 4.8 Patient programmer battery level on the THERAPY screen.

If the patient programmer batteries need immediate replacement, you will see one of the screens shown in Table 4.7.

Table 4.7 Patient programmer battery replacement screens

	The patient programmer batteries are low. You can finish programming. **Press any arrow on the NAVIGATOR key to clear the screen; then continue programming. Replace the patient programmer batteries before the batteries become depleted (refer to page 108).**
	The patient programmer batteries are depleted. Programming is not possible. **Replace the patient programmer batteries now (refer to page 108).**

Turning your neurostimulator ON or OFF

1. Hold the patient programmer over your neurostimulator with the patient programmer screen facing outward and press the NEUROSTIMULATOR ON or NEUROSTIMULATOR OFF key (Figure 4.9).
2. Verify that the appropriate ON or OFF icon is displayed on the THERAPY screen (Figure 4.9).

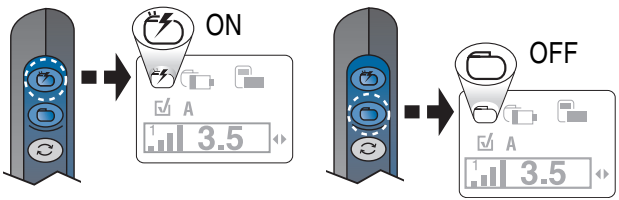


Figure 4.9 Turning your neurostimulator ON or OFF.

△ **Caution:** To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation) when stimulation is turned ON, decrease all

amplitudes to the lowest setting before adjusting the pulse width or rate and after turning OFF the neurostimulator.

3. If you have turned the neurostimulator OFF, decrease the program amplitudes to the lowest setting. For instructions, see “Increasing or decreasing a parameter (amplitude, pulse width, or rate)” on page 85.

Note: When you turn your neurostimulator ON or OFF, the patient programmer and neurostimulator are synchronized.

Scheduled Therapy

Scheduled Therapy allows your clinician to program therapy for a specific time of day. If your clinician programmed Scheduled Therapy, the SCHEDULED THERAPY () icon appears in the Group row.

An example of Scheduled Therapy is provided in Figure 4.10. The screens and timetable display the following:

- Group B is active most of the day and stimulation is ON
- Stimulation is OFF during sleep

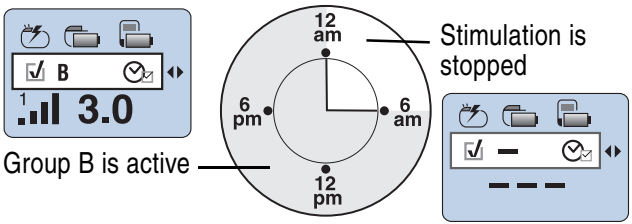


Figure 4.10 Example of Scheduled Therapy.

Note: You can still change groups or turn your neurostimulator ON or OFF when Scheduled Therapy is programmed.

Adjusting stimulation settings

There is often more than one way to change stimulation settings. These instructions describe the most common ways.

Notes:

- Ask your clinician to print a report with your programmed settings.
- When a stimulation setting is changed, you will see the change on the THERAPY screen.
- If audio is ON, you will hear one tone that means the change was effective. Three rapid tones mean there was a problem communicating with your neurostimulator and the change may not have occurred.

To receive the most effective therapy, some days you may need to adjust your stimulation several times; other days you may not need to adjust it at all. Your clinician will provide complete guidelines about when you may want to adjust your stimulation.

Table 4.8 provides general guidelines for adjusting your stimulation.

Table 4.8 Stimulation adjustment guidelines

Situation	Action
Stimulation is too strong	Decrease amplitude(s) or pulse width(s)
Stimulation is not strong enough	Increase amplitude(s) or pulse width(s)
Stimulation covers too much area	Decrease amplitude(s) or pulse width(s) or change to a different group
Stimulation does not cover painful area	Increase amplitude(s) or pulse width(s) or change to a different group
The pulses (tapping sensations) feel too slow	Increase rate
The pulses (tapping sensations) feel too fast	Decrease rate

Table 4.8 Stimulation adjustment guidelines (continued)

Situation	Action
You have unexpected changes in stimulation	1. Turn OFF the neurostimulator. 2. Decrease amplitude(s), turn ON the neurostimulator, adjust parameters, and slowly increase amplitude(s) to the desired level. **or** Change to a different group and turn ON the neurostimulator.
You have tried adjusting stimulation but are unable to find an effective setting.	Contact your clinician.
You will be passing through a theft detector or security device	Before engaging in these activities, consult "Appendix A: Electromagnetic Interference (EMI)" for details.
You will be using potentially dangerous equipment	
You will be having a medical procedure	

Changing a group

1. Hold the patient programmer over your neurostimulator with the screen facing outward and press the SYNC key. The THERAPY screen appears.
2. If needed, press the up arrow on the NAVIGATOR key to move the selection box to the Group row(Figure 4.11).

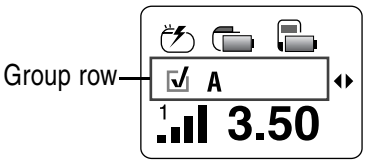


Figure 4.11 Group row on the THERAPY screen.

3. Press the left or right arrows on the NAVIGATOR key to move the selection box to the new group ☐ (Figure 4.12).

   △ **Caution:** Select the group that your clinician has recommended for the current activity or posture. Use of another group may result in uncomfortable or unexpected stimulation (jolting or shocking sensation) when stimulation is turned ON.

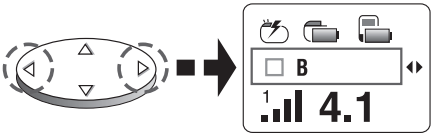


Figure 4.12 Moving to a new group.

4. Hold the patient programmer over your neurostimulator and press the SYNC key to send the change to your neurostimulator (Figure 4.13).
5. Verify that the new group is active on the THERAPY screen (Figure 4.13).

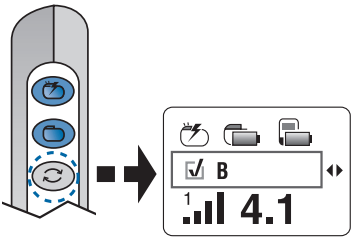


Figure 4.13 Making a group active.

Increasing or decreasing a parameter (amplitude, pulse width, or rate)

Notes:

- To increase a parameter, the neurostimulator must be ON.
- To decrease a parameter, the neurostimulator may be ON or OFF.

1. Hold the patient programmer over your neurostimulator with the screen facing outward and press the NEUROSTIMULATOR ON, NEUROSTIMULATOR OFF, or SYNC key. The THERAPY screen appears.

   Caution: To prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation) when stimulation is turned ON, decrease all amplitudes to the lowest setting before adjusting the pulse width or rate and after turning OFF the neurostimulator.

2. Verify that the group is active and that the selection box is located on the Parameter row.

3. Press the left ◀ or right ▶ arrow on the NAVIGATOR key to move the selection box to the desired parameter and program (Figure 4.14).

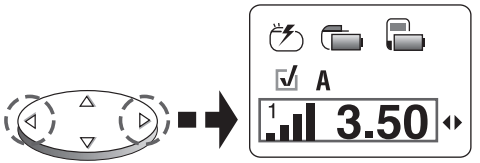


Figure 4.14 Moving to the desired parameter.

Notes:

- Only one parameter for one program can be displayed at a time on the parameter row. Scrolling to the right displays the amplitude (1 2) for each program, followed by the pulse width (1 2) for each program, and then the rate ( ). (Scrolling to the left reverses the order.)
- The program is designated by the number above the AMPLITUDE or PULSE WIDTH icon.

– There will not be a number above the RATE icon because the rate is the same for all programs in a group.

4. Hold the patient programmer over your neurostimulator and press the INCREASE ⊕ or DECREASE ⊖ key to increase or decrease the selected parameter as needed (Figure 4.15). The increase or decrease occurs immediately and is saved in the neurostimulator.

Figure 4.15 DECREASE and INCREASE keys.

Notes:

- Pressing and holding the INCREASE or DECREASE key changes the value every half-second.
- If one of the information screens in Table 4.9 appears, you tried to increase or decrease the parameter beyond the limits programmed by your clinician or beyond the capabilities of your neurostimulator.

Table 4.9 Parameter limit screens

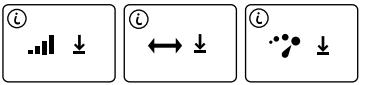
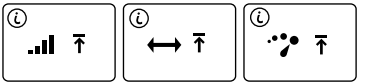
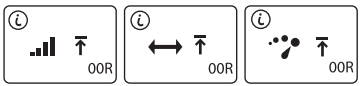
Lower limit 	You tried to decrease a parameter below the lowest value allowed (lower limit). **Press any arrow on the NAVIGATOR key to clear the screen.**
Upper limit 	You tried to increase a parameter above the highest value allowed (upper limit). **Press any arrow on the NAVIGATOR key to clear the screen.**

Table 4.9 Parameter limit screens (continued)

Upper limit (OOR)		You tried to increase a parameter above what your neurostimulator can deliver. **Press any arrow on the NAVIGATOR key to clear the screen.**

Using GroupAdjust (Models 37702, 37712, and 37713)

If your implanted neurostimulator is a Model 37702 PrimeADVANCED, a Model 37712 RestoreULTRA, or a Model 37713 RestoreADVANCED and your clinician enabled the GroupAdjust function, the GROUPADJUST icon ( ) will appear in the Parameter row (Figure 4.16). GroupAdjust may be used to adjust all program amplitudes for the active group at the same time.

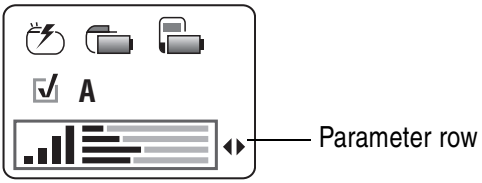


Figure 4.16 Group Adjust on the Parameter row.

When the INCREASE or DECREASE key is selected, the GROUPADJUST screen is displayed (Figure 4.17).

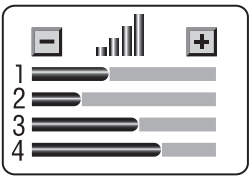


Figure 4.17 GROUPADJUST screen.

Each bar on the GROUPADJUST screen represents each program amplitude for the active group and the amount of adjustment available relative to the limits programmed by your clinician. These bars increase or decrease as you increase or decrease the amplitudes.

1. Hold the patient programmer over your neurostimulator with the screen facing outward and press the NEUROSTIMULATOR ON, NEUROSTIMULATOR OFF, or SYNC key. The THERAPY screen appears.

   Notes:

   – To increase the amplitude, the neurostimulator must be ON.

   – To decrease the amplitude, the neurostimulator may be ON or OFF.

2. Verify that the group is active ☑ and the selection box is located on the GROUPADJUST icon on the Parameter row (Figure 4.16).

3. Hold the patient programmer over your neurostimulator and press the INCREASE or DECREASE key. The GROUPADJUST screen appears.

4. Hold the patient programmer over your neurostimulator and press the INCREASE or DECREASE key to increase or decrease the amplitude as needed.

5. Once the desired levels are displayed, release the INCREASE or DECREASE key to save the amplitude adjustment and to return to the THERAPY screen.

Notes:

- One program amplitude (represented by one of the bars) may reach its upper or lower limit while the other program amplitudes have not.
- The program that has reached its upper or lower limit will stop increasing or decreasing while the other programs will continue increasing or decreasing until they have also reached their limits.
- When all programs in the group have reached either their upper or lower limits, an information screen will be

displayed stating that the limit has been reached (see Table 4.9 on page 88).

Using TARGETmyStim (Models 37702, 37712 and 37713)

If your implanted neurostimulator is a Model 37702 PrimeADVANCED, Model 37712 RestoreULTRA, or a Model 37713 RestoreADVANCED and your clinician has programmed TARGETmyStim, the TARGETMYSTIM icon ($\updownarrow_1$) will appear in the Parameter row (Figure 4.18). TARGETmyStim allows you to make adjustments to your therapy by moving the lead array (active electrodes) up or down one level.

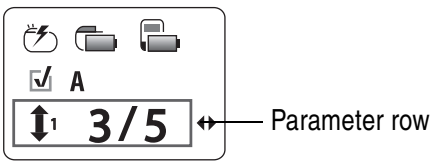


Figure 4.18 TARGETmyStim on Parameter row.

The small metal electrodes near the tip of the lead are not all active at the same time. Only

those electrodes that are active deliver the electrical pulses. Specific combinations or positions of active electrodes will deliver stimulation to a very specific pain site.

TARGETmyStim allows you to try specific electrode positions to determine which is best for your pain.

The numbers on the TARGETMYSTIM icon represent the electrode position for a program in the active group and the number of adjustments available (Figure 4.18 on 93). For example, 3/5 means the electrodes are in position 3 out of a possible 5 positions. The number of available positions will vary depending on how your clinician programmed your neurostimulator.

When the INCREASE or DECREASE key is selected, the TARGETMYSTIM screen is displayed showing the current position and the selected position (Figure 4.19).

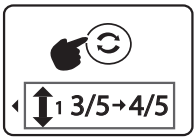


Figure 4.19 TARGETMYSTIM screen.

1. Hold the patient programmer over your neurostimulator with the screen facing outward and press the SYNC key. The THERAPY screen appears.
2. Verify that the group is active and the selection box is located on the TARGETMYSTIM icon on the Parameter row (Figure 4.18 on page 93).
3. Hold the patient programmer over your neurostimulator and press the INCREASE or DECREASE key. The TARGETMYSTIM screen appears.
4. Hold the patient programmer over your neurostimulator and press the INCREASE or DECREASE key to change active electrode positions as needed

5. Once the desired levels are displayed, press the SYNC key.

   Note: The patient programmer changes the electrode position, then the amplitude slowly increases until it reaches the programmed value. Pressing the INCREASE or DECREASE key will stop the amplitude increase before it reaches the programmed value

6. Press the left arrow on the NAVIGATOR key to return to the THERAPY screen.

Summary of keys

Figure 4.20 Patient programmer keys.

Table 4.10 Summary of keys

Key	Function
 ON  OFF	**Turns the neurostimulator ON or OFF .** • The patient programmer must be held over the neurostimulator while pressing the NEUROSTIMULATOR ON or OFF key. • Pressing either of these keys also automatically synchronizes the neurostimulator and patient programmer and displays the THERAPY screen.
 Sync	**Synchronizes the neurostimulator and patient programmer.** **Activates a selected group.** The patient programmer must be held over the neurostimulator while pressing the SYNC key.

Table 4.10 Summary of keys (continued)

Key	Function
 Decrease  Increase	**Decreases ▭ or increases ⊕ a parameter.** • The patient programmer must be held over the neurostimulator while pressing the INCREASE ⊕ or DECREASE ▭ key. • Pressing and holding the INCREASE ⊕ or DECREASE ▭ key changes the parameter every half-second. • To increase a parameter, the neurostimulator must be turned ON.
 Navigator	**Moves the selection box on the THERAPY screen.** The OPTIONS ◆▶ icon at the end of a row on the THERAPY screen indicates that the row continues.
 Power/ Backlight	**Turns the patient programmer power ON and OFF.** **Pressing and holding this key also turns the backlight ON and OFF. The backlight provides more light to the display.**

Preferences: Changing the audio, contrast, time, time/ number format

Patient programmer preferences are accessed from the Status row of the THERAPY screen. Table 4.11 lists the preference icons.

Table 4.11 Preference icons

Icons	Preference
	**Audio**
	**Contrast**
	**Time**
	**Time and number format**
	**Group name display (see page 105)**
	**Return to clinician settings**

1. Hold the patient programmer over your neurostimulator with the screen facing outward and press the SYNC key. The THERAPY screen appears.
2. Press the up arrow on the NAVIGATOR key to move the selection box to the Status row (Figure 4.21).

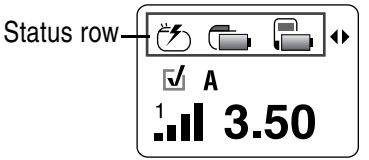


Figure 4.21 Accessing preferences from the Status row.

3. Press the left or right arrow on the NAVIGATOR key to move the selection box to the desired preference (Figure 4.22).

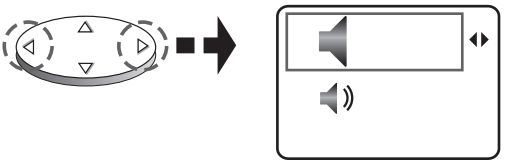


Figure 4.22 Moving to the desired preference.

4. Press the down ▼ arrow to move the selection box to the Change row (Figure 4.23).

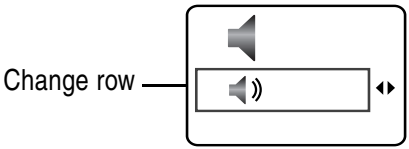


Figure 4.23 Change row for selected preference.

5. Follow the steps in Table 4.12 to change the selected preference.

Table 4.12 Changing preferences

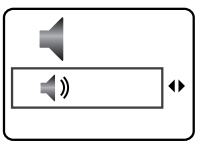
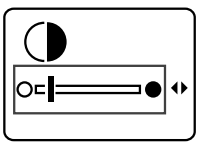
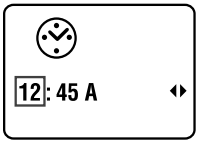
	**Audio** 1. Press the left ◀ or right ▶ arrow on the NAVIGATOR key to move the selection box to audio ON 🔊 or OFF 🔇. 2. Go to step 6, page 103.
	**Contrast** 1. Press the left ◀ or right ▶ arrow on the NAVIGATOR key to make the contrast lighter ○ or darker ●. 2. Go to step 6, page 103.

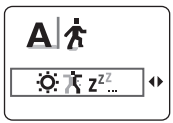
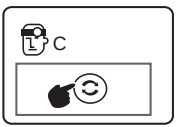
Table 4.12 Changing preferences (continued)



Time

1. Press the left ◀ or right ▶ arrow on the NAVIGATOR key to move the selection box to the hour, minutes, or time of day (**A** or **P**).
2. Press the INCREASE ⊕ or DECREASE ⊖ key to change the selection.
3. Press the up ▲ arrow on the NAVIGATOR key to return the selection box to the Status row.
4. Press the left ◀ or right ▶ arrow on the NAVIGATOR key to return to the THERAPY screen.
5. Press the SYNC ⟲ key to send the change to your neurostimulator.
6. To verify the time change, repeat steps 2 and 3 on page 100 to return to the TIME PREFERENCE screen.

Table 4.12 Changing preferences (continued)

	**Time and number format** 1. Press the left ◀ or right ▶ arrow on the NAVIGATOR key to move the selection box to a 12-hour clock and numbers with decimals or with a 24-hour clock and numbers with commas. 2. Go to step 6, page 103.
	**Group name display** **See page 105.**
	**Return to clinician settings** **See page 104.**

6. When the change is displayed on the screen, move the selection box to the Status (top) row.

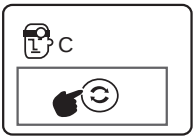
Note: The preference change is sent to the neurostimulator at the next synchronization.

7. Press the left  or right  arrow on the NAVIGATOR key to move to another preference or return to the THERAPY screen.

Changing to clinician settings

You can change the stimulation settings for the active group back to the original settings programmed by your clinician (Table 4.13).

Table 4.13 Changing to clinician settings



Clinician settings preference

1. Verify that the desired group is active ☑.
2. Complete steps 1-4 beginning on page 100.

Note: Clinician settings will be applied to the group that is indicated on the CLINICIAN SETTINGS PREFERENCE screen.

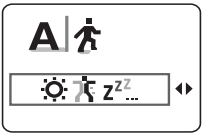
3. Press the SYNC key to send the change to your neurostimulator and return to the THERAPY screen.

Changing group names (Models 37702, 37712, and 37713)

If your implanted neurostimulator is a Model 37702 PrimeADVANCED, a Model 37712 RestoreULTRA, or a Model 37713 RestoreADVANCED and your clinician enabled the Group name (icons / text) function, you can change the group name displayed on the patient programmer screen (Table 4.14). You can change the group name displayed

on the screen to a letter (eg, A), an icon (eg,), or text (eg, Walk).

Table 4.14 Changing Group name preferences



Group name preferences

1. Complete steps 1-4 beginning on page 100
2. Press the left ◀ or right ▶ arrow on the NAVIGATOR key to move the selection box to one of the following:
   - Icons ( ),
   - Letters ( ), or
   - Text (**Abc**...).
3. Go to step 6, page 103.

Your clinician may enable the Group Name (icons / text) function to specify the groups to use for specific areas of coverage, activity, and time of use. Table 4.15 lists the Group name preferences that may be available.

Note: Use the definitions listed in Table 4.15 to understand the icon or text displayed on your patient programmer.

Table 4.15 Group name (icons / text)

Icon display	Text display[a]	Definition
	**Sit**	**Group for use when you are sitting**
	**Stand**	**Group for use when you are standing**
	**Lie**	**Group for use when you are lying**
	**Walk**	**Group for use when you are walking**
	**Sleep**	**Group for use when you are sleeping**
	**Write**	**Group for use when you are writing**
	**Day**	**Group for use during the day**
	**Night**	**Group for use during the night**
	**Back**	**Group for back pain**
	**L Leg**	**Group for left leg pain**

Table 4.15 Group name (icons / text) (continued)

Icon display	Text display[a]	Definition
	R Leg	Group for right leg pain
	Legs	Group for leg pain
	L Arm	Group for left arm pain
	R Arm	Group for right arm pain
	Arms	Group for arm pain
	Hand	Group for hand pain
	Foot	Group for foot pain

[a] The text display listed in this column will be displayed on the patient programmer exactly as shown in this column (ie, the text display will not be translated from English into local languages).

Replacing the patient programmer batteries

Always keep two new AAA alkaline batteries available for replacement. New batteries

provide about two months use, depending upon how often the patient programmer is used.

△ **Caution:** If the device will not be used for several weeks, remove the batteries from the device. A battery left in the device may corrode, causing damage to the electronic components.

1. Open the battery compartment cover (Figure 4.24).

Figure 4.24 Opening the battery cover.

2. Remove the depleted batteries.

3. Insert the new batteries as shown on the battery compartment label.
4. Close the battery compartment cover.
5. Dispose of old batteries according to local requirements.

Using the carrying case and labeling the patient programmer

The carrying case has a pouch to hold the patient programmer and the quick reference guide (Figure 4.25).

The case also has a loop on the back that attaches to a belt.

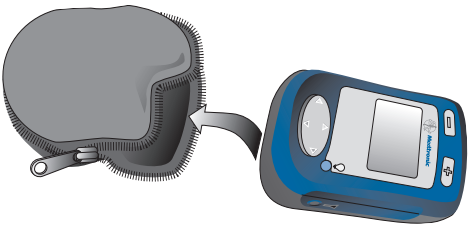


Figure 4.25 Insert the patient programmer into the case.

Place an identification label on the back of your patient programmer in case the patient programmer is lost (Figure 4.26).

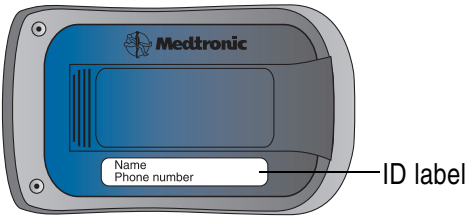


Figure 4.26 Place the adhesive label on the back of the patient programmer.

Optional detachable antenna

The detachable antenna is available if you have difficulty reaching the neurostimulator. It is also useful for viewing the patient programmer screen while you are adjusting stimulation.

Connecting the antenna

1. Place the antenna over your neurostimulator (Figure 4.27).

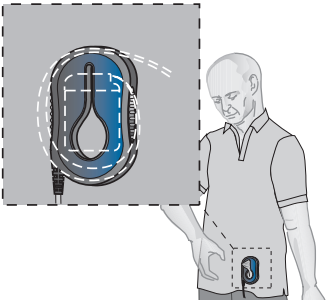


Figure 4.27 Place the antenna over your neurostimulator.

2. Pull the fabric of your clothing through the large opening in the antenna. Then, wedge the fabric in the narrow slit to secure the antenna in place (Figure 4.28).

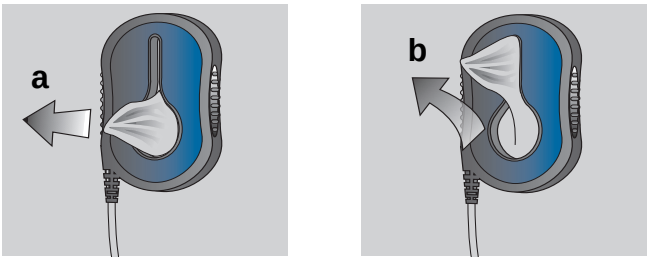


Figure 4.28 Pull the fabric through the slit (a) and wedge in place (b).

3. Push the antenna plug firmly into the antenna jack ( ) on the patient programmer (Figure 4.29).

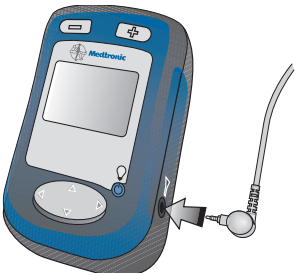


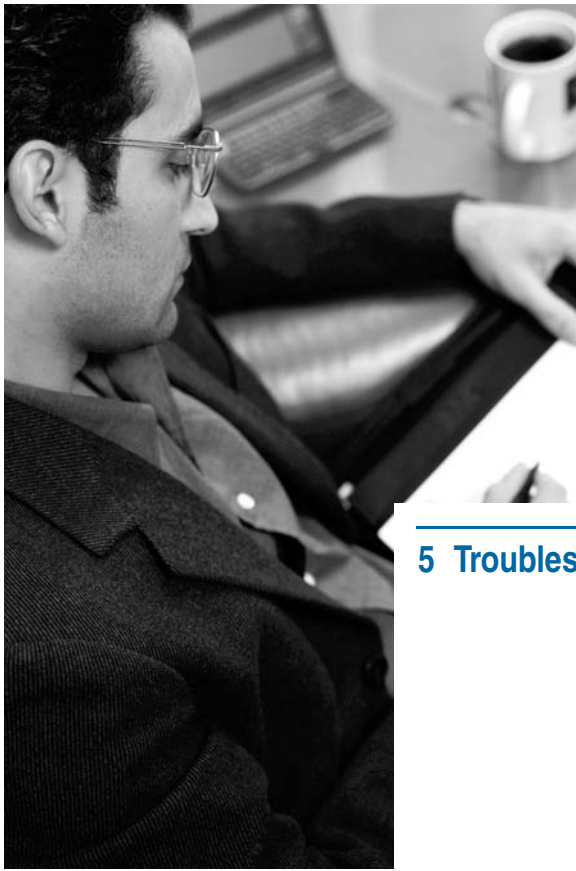
Figure 4.29 Insert the antenna plug into the antenna jack.

Using the antenna

After the antenna is connected, follow the instructions for using the patient programmer.

When you have finished using the patient programmer, grasp the antenna plug and pull it out.

△ **Caution:** Do not pull directly on the antenna cable to disconnect the cable from the programmer because this may damage the antenna cable.



5 Troubleshooting

This chapter will help you solve problems with your patient programmer. It also provides information on when to call your clinician.

Note: If you cannot solve a problem or if your problem is not described here, contact your clinician.

Patient programmer screens

The patient programmer displays warning (⚠), communication (⧗), and information (ⓘ) screens to provide you with information about your system, alert you to a problem with your system, or to guide you during patient programmer use.

Warning screens

Warning screens indicate a problem with the patient programmer, the antenna, or the neurostimulator. If the audio is ON, three

tones alert you to the message. Table 5.1 describes warning screens and provides instructions (**see blue text**) on how to resolve the problem and clear the screen.

Table 5.1 Warning screens

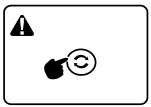
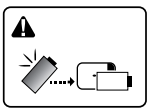
Screen	Cause and action
Synchronize programmer and neurostimulator 	The patient programmer and the neurostimulator must be synchronized. **Synchronize the patient programmer and neurostimulator.**
Replace the external neurostimulator batteries 	The external neurostimulator batteries are depleted and stimulation is not available. **Replace the external neurostimulator batteries now. Refer to the manual packaged with the external neurostimulator.**

Table 5.1 Warning screens (continued)

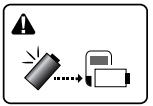
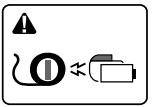
Screen	Cause and action
Replace the patient programmer batteries 	The patient programmer batteries are depleted. Programming is not possible. **Replace the patient programmer batteries now.**
Charge the rechargeable implanted neurostimulator battery 	The neurostimulator battery charge level is low and stimulation has stopped. **Charge the neurostimulator battery now. Refer to the manual packaged with the charging system.**

Table 5.1 Warning screens (continued)

Screen	Cause and action
	△ **Caution:** Charge the neurostimulator when you see a low battery (▭) screen on the patient programmer or recharger; this prevents the battery from overdischarging (see glossary). If the neurostimulator battery is allowed to overdischarge, charging is not possible; however, the clinician may be able to restore the battery function. Allowing the neurostimulator battery to overdischarge will permanently affect the neurostimulator in one of the following ways: • Battery function is restored; however, charging sessions may be more frequent because battery capacity has been reduced. • Battery function is not restored and the neurostimulator must be surgically replaced. Battery function is not restored because: - The neurostimulator battery is permanently damaged. - The neurostimulator battery has been overdischarged and restored twice before. The third time the battery is overdischarged, the neurostimulator will reach end of service. Surgery is required to replace the neurostimulator.

Table 5.1 Warning screens (continued)

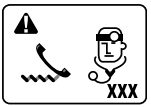
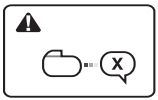
Screen	Cause and action
Call your doctor 	The system is not working correctly. Stimulation may have stopped. **Read the error code at the bottom of the screen.** **Error codes 0 to 252: Remove batteries from the patient programmer, wait several seconds, then re-insert the batteries. If the error message appears again, call your doctor.** **Other codes: Write down the code shown on the screen. Call your doctor.**
Call your doctor 	Your neurostimulator has reached end of service. Stimulation is not available. **Call your doctor.**
Call your doctor 	Your neurostimulator has been reset. Stimulation is not available. **Call your doctor.**

Table 5.1 Warning screens (continued)

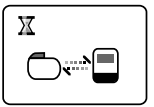
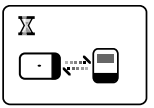
Screen	Cause and action
Device not supported 	The implanted device that you are attempting to communicate with is not compatible with the patient programmer. **Call your doctor.**

Communication screens

The communication screens show you that a process is in progress. Table 5.2 describes the communication screens for your neurostimulation system.

The communication screens automatically clear when the neurostimulation system finishes the process.

Table 5.2 Communication screens

Screen	Description and action
Communication 	The patient programmer is communicating with the implanted neurostimulator.
Communication 	The patient programmer is communicating with the external neurostimulator.

Information screens

The information screens show the programming status and the battery level for your patient programmer. The information screen also indicates the battery level of a rechargeable neurostimulator. If the audio is ON, three tones alert you to the message. Table 5.3 describes information screens and instructions on how to proceed (**see blue text**).

Note: Press any arrow on the NAVIGATOR key to clear an information screen.

Table 5.3 Information screens

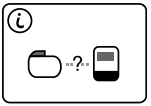
Screen	Description and action
Poor communication 	The patient programmer attempted to communicate with the implanted neurostimulator, but communication was unsuccessful. **Reposition the patient programmer over the implanted neurostimulator with the screen facing outward and try communication again.** **If using the detachable antenna, check that the antenna is connected properly, reposition the antenna and try communication again.**

Table 5.3 Information screens (continued)

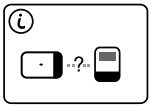
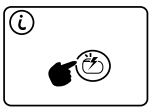
Screen	Description and action
Poor communication 	The patient programmer attempted to communicate with the external neurostimulator, but communication was unsuccessful. **Reposition the patient programmer over the external neurostimulator with the patient programmer screen facing outward and try communication again.** **If using the detachable antenna, check that the antenna is connected properly, reposition the antenna and try communication again.**
Press NEUROSTIMULATOR ON key 	You tried increasing a parameter value with the neurostimulator OFF. **Turn your neurostimulator ON and try communication again.**

Table 5.3 Information screens (continued)

Screen	Description and action
Upper limit (amplitude shown) 	You tried increasing a parameter (amplitude, pulse width, or rate) above the highest value allowed.
Upper limit 00R (amplitude shown) 	You tried increasing a parameter (amplitude, pulse width, or rate) above what your neurostimulator can deliver. **Decrease another parameter before increasing this parameter.** **Recharge the rechargeable neurostimulator battery (if applicable).** **Replace the external neurostimulator batteries (if applicable).**

Table 5.3 Information screens (continued)

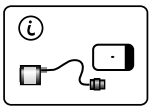
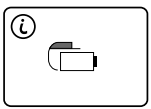
Screen	Description and action
Lower limit (amplitude shown) 	You tried decreasing a parameter (amplitude, pulse width, or rate) below the lowest value allowed.
Connect cable 	The cable to the external neurostimulator is loose or disconnected. **Connect the cable to the external neurostimulator. Turn the patient programmer OFF then ON again.**
Rechargeable implanted neurostimulator battery charge level is low 	The implanted neurostimulator battery charge level is low and stimulation will not be available soon. **Charge your implanted neurostimulator battery. Refer to the manual packaged with the charging system.**

Table 5.3 Information screens (continued)

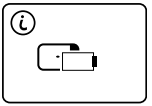
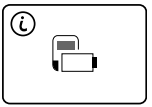
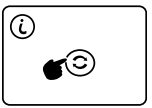
Screen	Description and action
External neurostimulator batteries are low 	The external neurostimulator batteries are low and stimulation will not be available soon. **Replace the external neurostimulator batteries. Refer to the manual packaged with the external neurostimulator.**
Patient programmer batteries are low 	The patient programmer batteries are low. You can finish programming. **Replace the patient programmer batteries before the batteries become depleted.**
Synchronize 	You tried increasing or decreasing a parameter for an inactive group. **Synchronize the patient programmer and neurostimulator.**

Table 5.3 Information screens (continued)

Screen	Description and action
Implanted neurostimulator is nearing end of service 	The implanted neurostimulator is nearing end of service. Stimulation will not be available soon. **Call your clinician to schedule a visit.** **You may clear this screen and return to the THERAPY screen by pressing any arrow on the NAVIGATOR key. This screen reappears daily. After clearing this screen, a low battery level icon appears on the Status row of the THERAPY screen**
POR 	The implanted neurostimulator has been reset. Stimulation is not available. **Call your clinician.** **You may clear this screen and return to the THERAPY screen by pressing any arrow on the NAVIGATOR key.**

Table 5.3 Information screens (continued)

Screen	Description and action
OOR 	The neurostimulator is unable to deliver the programmed settings. **Call your clinician.** **You may clear this screen and return to the THERAPY screen by pressing any arrow on the NAVIGATOR key.**

Possible problems and solutions

Table 5.4 will help you solve problems or identify when to call your clinician. Problems are described in the left column (**bold black text**). The right column lists possible causes of the problem (plain text) and how to correct the problem (**bold blue text**).

Note: If a problem is not solved after several attempts, or if a problem is not described here, contact your clinician.

Table 5.4 Troubleshooting problems

Problems	Causes and actions
Uncomfortable stimulation: You are too uncomfortable with the current stimulation to think about how to change it.	The selected group or stimulation settings are not suitable for your current activity or posture. **1. Turn the neurostimulator OFF.** **2. Reduce the amplitude for each program in the active group.** **3. Change the group if the active group is not one that is recommended by your clinician for your current activity or posture; or adjust the amplitude, pulse width, and rate to values that provide adequate pain relief.**

Table 5.4 Troubleshooting problems (continued)

Problems	Causes and actions
Delayed stimulation changes: You do not feel stimulation right away after turning ON the neurostimulator or you feel stimulation after turning OFF the neurostimulator.	Your clinician programmed SoftStart/Stop so that stimulation starts and stops gradually: **Allow about 8 seconds for your neurostimulator to turn ON and OFF.** **You may feel a residual effect after the neurostimulator is turned OFF.**
Intermittent stimulation: You feel stimulation only some of the time.	Your clinician may have programmed your neurostimulator to turn ON and OFF at regular intervals. **However, if you are not receiving adequate pain relief, contact your clinician.**

Table 5.4 Troubleshooting problems (continued)

Problems	Causes and actions
No stimulation: You do not feel stimulation but you think stimulation should be ON.	Stimulation is OFF. **Use your patient programmer to turn your neurostimulator ON.** Your clinician has programmed scheduled therapy and stimulation is scheduled to be stopped at this time. **If stimulation is desired, select another group and turn stimulation ON.** The amplitudes for each program in the active group are set too low to feel. **Use your patient programmer to increase the amplitude(s).**

Table 5.4 Troubleshooting problems (continued)

Problems	Causes and actions
Patient programmer is unresponsive: The display screen is blank when you press a key.	The patient programmer batteries are depleted. **Replace the patient programmer batteries.** The patient programmer batteries are in backwards. **Check the battery polarity and reinstall the patient programmer batteries.**
Dropped patient programmer: Your patient programmer falls off a cabinet or table.	The patient programmer is designed to withstand a short drop to a hard surface and still operate normally, even if the case is chipped or nicked. **Try the patient programmer; it should work.**

Table 5.4 Troubleshooting problems (continued)

Problems	Causes and actions
Fluid on the patient programmer: Fluid was spilled onto the patient programmer or the patient programmer was dropped into water.	The patient programmer is not waterproof, and water can damage the device. **Immediately remove the patient programmer from the water, then dry the patient programmer with a towel dampened with clean tap water.** **Remove the batteries, then allow the battery compartment to air dry at room temperature for 24 hours.**

User assistance

The patient programmer has been designed and tested to provide trouble-free service. If repair or service is needed, contact your clinician or a Medtronic sales office. Refer to the Medtronic contacts at the end of this manual.

The serial number is located in the battery compartment. This number identifies each patient programmer. If you contact Medtronic about your patient programmer, refer to the serial number.

If your patient programmer stops working – First try the steps in Table 5.4 on page 132. Otherwise, contact your clinician.

If you lose your patient programmer – Contact your clinician to order a new patient programmer.

! USA To register the patient programmer for service covered by the warranty, complete and mail the warranty registration.

6 Maintenance

This section describes how to care for and dispose of your patient programmer and accessories.

Cleaning and care

Follow these guidelines to ensure that the patient programmer and accessories function properly.

△ **Caution:** If the device will not be used for several weeks, remove the batteries from the device. A battery left in the device may corrode, causing damage to the electronic components.

- Keep the device out of the reach of children and pets.
- Use the device only as explained to you by your clinician or as discussed in this manual.

- Follow all warnings and precautions in chapter 2 “Important therapy information” and chapter 7 “Appendix A: Electromagnetic interference (EMI)”.
- Handle the device with care. Do not drop, strike, or step on the device.
- Do not dismantle or tamper with the device.
- Clean the outside of the device with a damp cloth when necessary. Mild household cleaners will not damage the device or labels.
- The device is not waterproof. Do not allow moisture to get inside the device.
- Keep fresh batteries available.
- Replace low or depleted batteries.

Safety and technical checks

Periodic safety and technical checks or periodic maintenance of the patient programmer are not required. The patient programmer contains no user-serviceable parts. If repair or service is needed, contact your clinician or a Medtronic sales office. Refer to the Medtronic contacts at the end of this manual.

Battery and programmer disposal

Dispose of depleted batteries and worn out devices according to local requirements. If you no longer need your programmer and would like to donate it, contact your clinician.

Neurostimulator disposal

The implanted device should be removed before burial or cremation. In some countries, removal of battery-powered implantable devices is required before burial because of environmental concerns. Also, the device should be removed before cremation. The cremation process causes the battery to explode. Explanted devices should not be resterilized or reimplanted.

Declaration of conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment, and Directive 90/385/EEC on Active Implantable Medical Devices.

For additional information, contact Medtronic. Refer to the list of Medtronic contacts at the end of this manual.

Specifications

Table 6.1 Patient programmer specifications

Item	Specification
Power source	2 AAA alkaline batteries (non-rechargeable, LR03)
Operating temperature	9°C to 43°C (49°F to 110°F)
Storage temperature	-40°C to 65°C (-40°F to 150°F)
Operating/storage relative humidity	30% to 95%
Operating/storage atmospheric pressure	70 kPa to 106 kPa (20.7 in Hg to 31.3 in Hg)
Size (approximate)	9.4 cm x 5.6 cm x 2.8 cm (3.7 in x 2.2 in x 1.1 in)
Weight, including batteries (approximate)	111 g (3.9 oz)
Battery life	2 months (average) for alkaline batteries
Mode of operation	Continuous

Table 6.2 Implanted neurostimulation system specifications

Description	Specifications
Typical materials in contact with human tissue[a]	
Neurostimulator	Titanium
	Polyurethane
	Silicone rubber
	Silicone medical adhesive
	Polysulfone[b]
Lead	Polyurethane Platinum iridium
Extension	Polyurethane

[a] For a complete list of materials in contact with human tissue, contact your clinician.

[b] Polysulfone is contained in the rechargeable neurostimulators only.

7 Appendix A: Electromagnetic interference (EMI)

Please review “Electromagnetic interference (EMI)” on page 24 and Table 2.1 on page 27 for additional information.

Before any medical procedure is begun, always inform any health care personnel that you have an implanted neurostimulation system. The potential for the following effects results from an interaction of the neurostimulation system and equipment — even when both are working properly.

Contraindication

Diathermy – Inform anyone treating you that you CANNOT have any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) anywhere on your body because you have an implanted neurostimulation system. Energy from

diathermy can be transferred through your implanted system, can cause tissue damage, and can result in severe injury or death.

Diathermy can also damage parts of your neurostimulation system. This can result in loss of therapy from your neurostimulation system, and can require additional surgery to remove or replace parts of your implanted system.

Personal injury or device damage can occur during diathermy treatment when:

- the neurostimulation system is turned ON or OFF.
- diathermy is used anywhere on your body (not just where your neurostimulation system is located).
- diathermy is used to deliver heat or no heat.
- any component of your neurostimulation system (lead, extension, neurostimulator) remains in your body.

Warnings

EMI from the following medical procedures or equipment can damage the device, interfere with device operation, or cause you harm. If these procedures or equipment are required, the guidelines below must be followed:

Defibrillation / cardioversion – When you are in ventricular or atrial fibrillation, the first consideration is your survival. External defibrillation or cardioversion can damage a neurostimulation system and cause induced electrical currents through the lead and extension. These induced electrical currents could injure you. The current flowing through the neurostimulation system should be minimized as follows:

- Paddles should be positioned as far from the neurostimulator as possible.
- Paddles should be positioned perpendicular to the neurostimulation system.

- The lowest clinically appropriate energy output (watt seconds) should be used.

After external defibrillation, your doctor should confirm that the neurostimulation system is working as intended.

Electrocautery – If electrocautery tools are used near an implanted device or contacts a device, the following effects can occur:

- The insulation on the lead or extension can be damaged, causing the lead or extension to fail or causing induced currents that can damage tissue or stimulate or shock you.
- The neurostimulator can be damaged, stimulation can be temporarily decreased or increased, or the neurostimulator can be turned OFF because the neurostimulator was reset to power-on-reset values (requiring your health care provider to reprogram your neurostimulator).

When electrocautery is necessary, these precautions must be followed:

- The neurostimulator should be turned OFF before using electrocautery.
- Bipolar cautery should be used.
- If unipolar cautery is necessary:
  - only low-voltage modes should be used.
  - the lowest possible power setting should be used.
  - the current path (ground plate) should be kept as far away as possible from the neurostimulator, extension, and lead.
  - full-length operating-room-table grounding pads should not be used.
- After electrocautery, your doctor should confirm that the neurostimulator is working as intended.

High-output ultrasonics / lithotripsy – Use of high-output ultrasonics or lithotripsy is not recommended if you have an implanted neurostimulation system. If lithotripsy must be used, the beam should

not be focused within 15 cm (6 in) of the neurostimulator.

Magnetic resonance imaging (MRI) – An MRI examination of the head only may be safely performed under certain specific conditions.* However, Medtronic recommends that an MRI using a radiofrequency (RF) transmit body coil should not be prescribed for you if you have any part of an implanted neurostimulation system. Exposing you to an MRI using a radiofrequency (RF) transmit body coil or not following the specific conditions indicated above can cause tissue damage and can result in severe injury or death.

*Please have your health care professional contact Medtronic for specific MRI guidelines for head-only MRI scans. Contact information is found on the last page of this manual.

The known potential risks are as follows:

- Induced electrical currents during an MRI using a radiofrequency (RF) transmit body coil can cause heating of the

neurostimulation system, especially at the lead-electrode site, which can cause tissue damage and can result in severe injury or death. Induced electrical currents can also stimulate or shock you.

Note: This warning applies even if only a lead or an extension is implanted in your body.

Factors that increase the risks of heating and injury include, but are not limited to, the following:

- High MRI Specific Absorption Rate (SAR) Radio Frequency (RF) power levels
- Lower impedance leads or extensions (Medtronic product names or model numbers designated with a “Z”, an “LZ”, or “Low Impedance”)
- MRI RF transmit coil that is near or extends over the implanted lead
- Implanted leads with small surface area electrodes

  - Short distances between lead electrodes and tissue that is sensitive to heat

- An MRI can permanently damage the neurostimulator, requiring it be removed or replaced.
- An MRI can affect neurostimulator operation. The MRI can also reset the neurostimulator to power-on-reset values requiring your health care provider to reprogram your neurostimulator.
- The neurostimulator can move within the implant pocket and align with the MRI field, resulting in discomfort or reopening of a recent implant incision.

In addition, the MRI image can be degraded, distorted, or blocked from view by your implanted neurostimulation system.

Radiofrequency (RF) / microwave ablation – Safety has not been established for radiofrequency (RF) or microwave ablation in patients with an implanted neurostimulation system. Induced electrical

currents can cause heating, especially at the lead electrode site, resulting in tissue damage.

Theft detectors and security devices – Use care when approaching theft detector and security devices (such as those found in airports, libraries, and some department stores). When approaching these devices, do the following:

1. Show the security personnel your patient identification card for the neurostimulator and ask for a manual search. Security personnel may use a handheld security wand but ask them not to hold the security wand near the neurostimulator any longer than is needed.
2. If you must pass through the theft detector or security screening device, turn your neurostimulator OFF, approach the center of the device and walk through normally.

a. If two security gates are present, walk through the middle, keeping as far away as possible from each gate.

b. If one gate is present, walk as far away as possible from it.

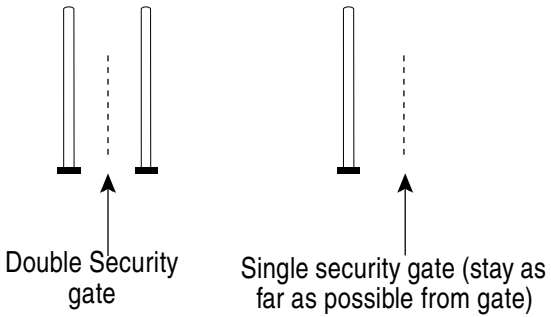


Figure 7.1 Approaching security gates.

Note: Some theft detectors might not be visible.

3. Proceed through the security device. Do not linger near or lean on the security device.

4. After you pass through the security device, turn your neurostimulator ON again.

Precautions

EMI from the following equipment is unlikely to affect your neurostimulation system if the guidelines below are followed:

Bone growth stimulators – The coils of an external magnetic field bone growth stimulator should be kept 45 cm (18 in) away from the neurostimulation system. When a bone growth stimulator is used, your doctor should ensure that both the bone growth stimulator and neurostimulator are working as intended.

Dental drills and ultrasonic probes – The neurostimulator should be turned OFF and the drill or probe should be kept at least 15 cm (6 in) away from the neurostimulator.

Electrolysis – The neurostimulator should be turned OFF, and the electrolysis wand should be kept at least 15 cm (6 in) away from the neurostimulator.

Electromagnetic field devices – The following equipment or environments should be avoided:

- Antennas of citizen band (CB) or ham radios
- Electric arc welding equipment
- Electric induction heaters
- Electric steel furnaces
- High-power amateur transmitters
- High-voltage areas (safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment
- Magnets and other equipment that generate strong magnetic fields
- Microwave communication transmitters (safe if outside the fenced area)
- Perfusion systems
- Resistance welders

- Television and radio transmitting towers (safe if outside the fenced area)

If you suspect that equipment is interfering with the neurostimulation system, do the following:

1. Move away from the equipment or object.
2. If possible, turn off the equipment or object.
3. Then, if necessary, use the patient programmer to return the neurostimulator to the desired ON or OFF state.
4. Inform the equipment owner or operator about the interference.

If the above actions do not resolve the effects of the interference, or you suspect that your therapy is not the same after exposure to EMI, contact your doctor.

Laser procedures – The neurostimulator should be turned OFF, and the laser should be directed away from the neurostimulation system.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (eg, electroconvulsive therapy, transcranial magnetic stimulation) in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Radiation therapy – High radiation sources such as cobalt 60 or gamma radiation should not be directed at the neurostimulation system. If radiation therapy is required near the neurostimulation system, lead shielding should be placed over the device to help prevent damage.

Transcutaneous electrical nerve stimulation (TENS) – TENS electrodes should not be placed so that current passes over any part of the neurostimulation system. If you feel that the TENS unit might be interfering with your neurostimulator,

discontinue using the TENS until you talk with your doctor.

Notes

Household items – Most household appliances and equipment that work properly and are properly grounded will not interfere with the neurostimulation system. The following equipment is safe if you follow these guidelines:

- Computer disk drives: Keep the neurostimulator away from disk drives.
- Induction range: Keep the neurostimulator away from the burners while the burners are turned on.
- Freezer, refrigerator, or storm doors: Do not lean against the magnetic strip that holds the door closed.
- Power tools: Keep the motor away from the neurostimulator, lead, and extension.

- Radio frequency sources: Keep AM/FM radios, and cellular, cordless, and conventional telephones at least 10 cm (4 in) away from the implanted neurostimulator.
- Sewing machines or salon hair dryers: Keep the neurostimulator away from the motors.
- Stereo speakers and radios for the home or car: Do not lift or carry them close to or touching the part of your body where the neurostimulator is located.

Other medical procedures – EMI from the following medical procedures is unlikely to affect your neurostimulation system:

- Computerized axial tomography (CT or CAT) scans
- Diagnostic ultrasound (eg, carotid scan, doppler studies)

  Note: To minimize potential image distortion, the neurostimulator should be turned OFF and the transducer kept

15 cm (6 in) away from the neurostimulation system.

- Diagnostic X-rays or fluoroscopy

  Note: Tight pressure in the area of your neurostimulator, such as used during mammography, can damage the neurostimulator or disconnect components of your neurostimulation system. This will require surgery to replace or repair the neurostimulation system. X-ray equipment should be adjusted so it does not squeeze the neurostimulator too tightly.

- Magnetoencephalography (MEG)
- Positron Emission Tomography (PET) scans

Therapeutic magnets (eg, magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep the magnet at least 25 cm (10 in) away from your neurostimulator. Magnetic fields of 10 gauss or less will generally not affect the neurostimulator.

Glossary

Amplitude – The strength or intensity of an electrical pulse.

Caution – A statement describing actions that could result in damage to or improper functioning of a device.

Charging system – Equipment used to charge the battery inside an implanted neurostimulator.

Clinician – A healthcare professional such as a doctor or nurse.

Clinician programmer – A device used by a clinician to send instructions to a neurostimulator.

Contraindication – A condition or circumstance when a person should not have a neurostimulation system.

Diathermy – A medical treatment applied to the outside of the body that delivers energy into the body. Three types of energy that can be used are shortwave, microwave, and

ultrasound. Depending on the power level used, diathermy devices may or may not produce heat within the body. This treatment is typically used to relieve pain, stiffness and muscle spasms, reduce joint contractures, reduce swelling and pain after surgery, and promote wound healing.

Electrode – A metal piece near the tip of the lead. Electrodes deliver electrical pulses to the area where your pain signals will be blocked.

Electromagnetic interference (EMI) – A strong field of energy near electrical or magnetic devices that could prevent the neurostimulator from functioning properly.

EOS – End of service (EOS). A notification that the neurostimulator has reached scheduled end of service. At EOS, the neurostimulator no longer delivers the electrical pulses that block pain signals.

ERI – Elective replacement indicator (ERI). A notification that the neurostimulator is nearing scheduled end of service.

Extension – A thin wire covered with a protective coating that connects the neurostimulator to a lead.

External neurostimulator (ENS) – See Neurostimulator.

Group – Combined programs that provide stimulation to one or more pain sites. Each group may be defined for a different activity, symptom, or time of day.

Group row – The middle row on the THERAPY screen. This row includes groups that a patient can change.

Implantable neurostimulator (INS) – See Neurostimulator.

Indication – The purpose of the neurostimulation system and the medical condition for which it may be implanted.

Lead – A thin wire with protective coating that has metal electrodes on one end and a connector on the other.

Neurostimulation system – Components that deliver electrical pulses to block pain signals as they move to the brain.

Neurostimulator – The power source of a neurostimulation system. It contains the battery and electronics that control the stimulation you feel.
– An external neurostimulator is carried outside the body. During test stimulation, it is used to determine whether or not stimulation is effective.
– An implanted neurostimulator is placed inside the body. If stimulation is effective during test stimulation, the neurostimulator is implanted.

Overdischarge – The neurostimulator battery continues to lose charge even after you see a low battery () screen. Eventually, the battery loses enough charge to permanently affect the neurostimulator. If this occurs, the battery is overdischarged.

Parameter – One of three stimulation settings that adjust the electrical pulse: amplitude, pulse width, and rate.

Parameter row – The bottom row on the THERAPY Screen. Icons indicate the parameters that a patient can adjust.

Patient programmer – A hand-held device that allows you to turn your neurostimulator ON and OFF. It is also used to adjust some stimulation settings.

Program – Stimulation directed to a specific pain site.

Precaution – See Caution.

Pulse width – The length or duration of an electrical pulse.

Rate – The number of electrical pulses delivered each second.

Settings – See Stimulation settings.

SoftStart/Stop – This feature, programmed by your clinician, starts and stops stimulation gradually by slowly increasing or decreasing to the programmed amplitude or OFF.

Spinal cord – This is your body's information center. Nerve signals from the entire body travel to your spinal cord, and then to your brain.

Status row – The top row on the THERAPY screen. Icons represent information about the neurostimulator and the patient programmer.

Stimulation – The delivery of electrical pulses to the area where pain signals are blocked as they move to the brain. Stimulation blocks some pain signals from reaching the brain.

Stimulation settings – Refers to all the features assembled to define the stimulation you feel. The clinician programs all stimulation. You can adjust some stimulation settings within clinician-defined limits.

Synchronize – The process of sending and receiving information between the patient programmer and neurostimulator.

Test stimulation – The period of time when an external neurostimulator is used to determine if stimulation blocks the pain signals effectively.

Therapy – Treatment of a disease or condition. When neurostimulation therapy is prescribed, a neurostimulation system is used to deliver stimulation to one or more pain sites.

THERAPY screen – The main screen displayed on the patient programmer.

Warning – A statement describing an action or situation that could harm the patient.

Warning screen – A screen displayed on the patient programmer that alerts you to a problem with the programmer, antenna, or neurostimulator.

Index

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